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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,462	11/13/2003	Jan Otto Solem	51533/MEG/E303	2503

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,462	SOLEM ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/31/05; 3/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed November 13, 2003 has been entered. The change to the specification has been approved by the examiner. All pending claims 1-25 are being considered for further examination on the merits.

Interference

2. The examiner acknowledges that claims 1-25 have been copied from U.S. Patent Application Publication 2002/0169504 A1 to application 09/855,945. The claims are the same or substantially the same as claims 1, 3-10, 13, 15-18 and 31-38 of 2002/0169504 A1.

3. Applicant should note that 09/855,945 has issued as U.S. Patent No. 6,800,090 and that the patented claims are not the same as the claims in 2002/0169504 A1.

Priority

4. The first sentence of the specification regarding continuity information must be updated to indicate that 09/345,475 is now U.S. Patent No. 6,210,432.

Information Disclosure Statement

5. The Information Disclosure Statements filed on January 31, 2005 and March 31, 2005 have been entered. An initialed and signed copy of each IDS is enclosed.

Specification

6. The disclosure is objected to because of the following informalities:

a) On page 4, line 14, "patient" should be changed to --patients--.

b) On page 8, line 12, "finaly" should be changed to --finally--.

c) On page 9, line 20, "Obviosly" should be changed to --Obviously--.

d) On page 10, lines 19, 22, and 24, and page 11, line 2, the commas in each of the numbers should be changed to periods.

e) On page 14, line 15, "instrument 11" should be changed to --instrument 12--.

Appropriate correction is required.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not disclose a guide wire engaging structure at at least one of the opposed ends of the mitral valve annulus device (claim 3), the guide wire engaging structure including a bore dimensioned to permit the guide wire to pass therethrough (claim 4), a guide wire confining channel extending between the opposed ends (claim 5), the bore of the engaging structure being cylindrical in configuration (claim 6), and a guide wire confining channel extending between the opposed ends and aligned with the bore (claim 7).

With respect to claim 15, the specification does not disclose step (D) of advancing the guide tube to the coronary sinus of the heart on the guide wire with the guide wire within the inner lumen of the guide tube as occurring after step (B) of advancing the guide wire to the coronary sinus. Also, the specification does not disclose step (I) of engaging the introducer with

the device as occurring after steps (G) and (H) of placing the device and introducer onto the guide wire. According to pages 14-15, lines 20-18 of the specification, first the guide tube is introduced into the venous system (it is not disclosed that the guide tube is advanced to the coronary sinus). Second, the guide wire is advanced through the guide tube and via the venous system to the coronary sinus. Third, the aggregate of elongate body, stabilizing instrument and cover sheath is pushed through the guide tube and the venous system to the coronary sinus riding on the guide wire. The broad disclosure of the "aggregate...riding on the guiding wire" on page 15, lines 6-8 without any further explanation is not sufficient to support that the device and the introducer are placed onto the guide wire.

With respect to claim 18, there is no support in the specification for the step of advancing the device on the guide wire. Again, the broad disclosure of the "aggregate...riding on the guiding wire" on page 15, lines 6-8 is not sufficient to support this claim limitation. Therefore, there is also no support for the step of mounting an elongate flexible introducer onto the guide wire (claim 19). With respect to claim 23, see explanation to claim 15, supra, for the specification not supporting the limitation of advancing the guide tube to the coronary sinus over the guide wire.

Because the above limitations were claimed at the time the application was filed, they are not considered new matter. They must now be included into the specification. The claims containing these limitations and claims dependent thereon, specifically claims 3-7 and 15-25, do not receive priority benefit of the parent applications. The effective filing date of these claims is filing date of the application, which is November 13, 2003. The effective filing date of claims 1, 2 and 8-14 is June 30, 1999.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 3-7 and 15-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al. (USPAP 2002/0169504 A1).

Alferness et al. disclose an assembly for effecting the condition of a mitral valve annulus of a heart with all the elements of claims 3-7. See claims 3-7 of Alferness et al. Alferness et al. also disclose a method of deploying a mitral valve annulus constricting device within the coronary sinus of a heart with all the elements of claims 15-17. See claims 16-18 of Alferness et al. Alferness et al. also disclose a method of deploying a mitral valve annulus reshaping device within the coronary sinus of a heart with all the elements of claims 18-25. See claims 31-38 of Alferness et al.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 2 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (USPN 5,170,802, as cited in applicant's IDS) in view of Dahl et al. (USPN 5,531,779).

Mehra discloses an assembly with all the elements of claim 1, but is silent specifically to the device reshaping the mitral valve annulus when in the coronary sinus of the heart. See Figures 1, 5 and 6, column 3, lines 34-36 and column 4, lines 8-40 for an assembly including a guide wire (118) configured to be advanced to the coronary sinus (12) and a device (100) in the form of a self-expanding electrode configured to be received on the guide wire (118) and advanced into the coronary sinus on the guide wire (118). See line 10 of the abstract for the device being used in the coronary sinus or the great vein of the heart, and column 2, lines 30-36 for the inner lumen of the device in the expanded configuration having an inner diameter approximately equal to the inner diameter of the vessel. Dahl et al. teach an electrode (14) that is sized and configured to be inserted into the great vein of the inferior vena cava. See Figure 1 and column 3, lines 43-52. The electrode is constrained to a reduced diameter for introduction into the vein and self-expands to its original diameter (which is selected in accordance with the vein into which the device is to be implanted so that the stent will intimately contact the inner wall of the vein when in place) once the constraining member is removed. See column 2, lines 30-38. The inferior vena cava is the largest venous structure in the body and has a mean diameter of 19-20mm, as evidenced by Siskin (*Inferior Vena Cava Filters*, see sections "Normal anatomy" and "Assessing the IVC"; http://www.emedicine.com/radio/topic762.htm). The coronary sinus is typically 10mm at its largest diameter, as evidenced by Smits (USPN 6,006,122; see abstract and column 4, lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Dahl et al. to modify the device of Mehra by

making it sized for insertion into the great vein of the inferior vena cava. Therefore, if the modified device of Mehra is placed and deployed within the coronary sinus, which has a smaller diameter than the inferior vena cava, expansion of the device to its original diameter (which corresponds to the diameter of the inferior vena cava) will certainly apply a force along a portion of the atrial wall of the coronary sinus and reshape the mitral valve annulus. When used in this manner, the device of Mehra is providing as a mitral valve annulus device. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The modified device of Mehra is capable of reshaping the mitral valve annulus when in the coronary sinus, thereby making the assembly capable of effecting the condition of the mitral valve annulus.

Claim 2, see Figure 5 for the device (100) being configured to be slidingly received on the guide wire (118).

Claims 9 and 10, see column 4, lines 49-52 for the device being made from certain metals, which by nature have some radiopacity, and therefore being visible under x-ray.

Claims 11 and 12, see Figures 5 and 6 and column 4, lines 27-35 for an elongated introducer (116) configured to be slidingly received on the guide wire (118) proximal to the device (100).

Claim 13, see Figures 5 and 6 and column 4, lines 34-37 for a friction fit between the device (100) and the introducer (116) providing as the locking mechanism. Because the

introducer (116) can be pulled back passed the device (100), the locking mechanism is considered releasable.

Claim 14, see Figure 5 and column 4, lines 27-35 for a guide tube (121) having an inner lumen dimensioned for receiving the guide wire (118) and the device (100) and introducer (120) when the device and introducer are received on the guide wire.

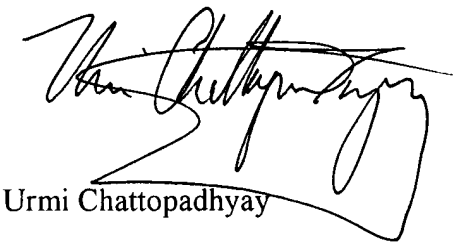
12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra in view of Dahl et al. as applied to claim 1 above, and further in view of Sullivan (USPN 5,209,730).

Mehra, as modified by Dahl et al., discloses an assembly for effecting the condition of the mitral valve annulus with all the elements of claim 1, but is silent to the additional limitation of the guide wire being formed of a material visible under X-ray, as required by claim 8. Sullivan teaches that it is old and well known in the art to include a radiopaque material to the distal end of a guide wire in order for placement of the guide wire to be monitored by x-ray, which then aids in the placement of a catheter. See column 1, lines 23-29. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Sullivan to modify the guide wire of Mehra by making the distal end from a radiopaque material in order for placement of the guide wire within the coronary sinus to be monitored by x-ray, which then will aid in the placement of the introducer (116) and device (100).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

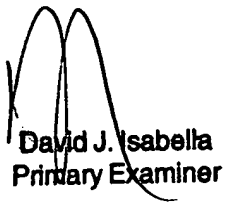
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner